**TRANSMITTAL  
FORM**

(to be used for all correspondence after initial filing)

|   |                        |                      |
|---|------------------------|----------------------|
| <b>TRANSMITTAL<br/>FORM</b><br>(to be used for all correspondence after initial filing) | Application Number     | 09/632,722           |
|   | Filing Date            | August 4, 2000       |
|   | First Named Inventor   | Himmelspach, Michele |
|   | Art Unit               | 1653                 |
| Total Number of Pages in This Submission  | Examiner Name          | Robinson, Hope A.    |
|   | Attorney Docket Number | 20695C-005700US      |

**ENCLOSURES (Check all that apply)**

|   |  |  |
|---|--|--|
| <input checked="" type="checkbox"/> Fee Transmittal Form<br><input type="checkbox"/> Fee Attached<br><input type="checkbox"/> Amendment/Reply<br><input type="checkbox"/> After Final<br><input type="checkbox"/> Affidavits/declaration(s)<br><input type="checkbox"/> Extension of Time Request<br><input type="checkbox"/> Express Abandonment Request<br><input checked="" type="checkbox"/> Information Disclosure Statement<br><input type="checkbox"/> Certified Copy of Priority Document(s)<br><input type="checkbox"/> Response to Missing Parts/Incomplete Application<br><input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53 | <input type="checkbox"/> Drawing(s)<br><input type="checkbox"/> Licensing-related Papers<br><input type="checkbox"/> Petition<br><input type="checkbox"/> Petition to Convert to a Provisional Application<br><input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address<br><input type="checkbox"/> Terminal Disclaimer<br><input type="checkbox"/> Request for Refund<br><input type="checkbox"/> CD, Number of CD(s) | <input type="checkbox"/> After Allowance Communication to Group<br><input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences<br><input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief)<br><input type="checkbox"/> Proprietary Information<br><input type="checkbox"/> Status Letter<br><input checked="" type="checkbox"/> Other Enclosure(s)<br>(please identify below):<br>Return Postcard, copies of forty-two (42) cited references |
| Remarks   |  | The Commissioner is authorized to charge any additional fees to Deposit Account 20-1430.   |

**SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT**

|                    |  |                 |
|--------------------|--|-----------------|
| Firm or Individual | Townsend and Townsend and Crew LLP<br>Scott L. Aussenhus | Reg. No. 42,271 |
| Signature          |  |                 |
| Date               | 09-30-03   |                 |

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| Typed or printed name | Nicole M. Wartell |      |         |
| Signature             |                   | Date | 9/30/03 |

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PTO/SB/17 (08-03)

# FEE TRANSMITTAL for FY 2003

Effective 01/01/2003. Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$ ) 180

Complete if Known

Application Number 09/632,722  
Filing Date August 4, 2000  
First Named Inventor Himmelspace, Michele  
Examiner Name Robinson, Hope A.  
Art Unit 1653  
Attorney Docket No. 20695C-005700US

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## METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit Card ☐ Money Order ☐ Other ☐ None

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Account  
Number

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Deposit  
Account  
Name

Townsend and Townsend and Crew LLP

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- ☒ Charge fee(s) indicated below ☒ Credit any overpayments  
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☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.

## FEE CALCULATION

### 1. BASIC FILING FEE

Large Entity Small Entity

| Fee Code | Fee (\$) | Fee Code | Fee (\$) | Fee Description        | Fee Paid |
|----------|----------|----------|----------|------------------------|----------|
| 1001     | 750      | 2001     | 375      | Utility filing fee     |          |
| 1002     | 330      | 2002     | 165      | Design filing fee      |          |
| 1003     | 520      | 2003     | 260      | Plant filing fee       |          |
| 1004     | 750      | 2004     | 375      | Reissue filing fee     |          |
| 1005     | 160      | 2005     | 80       | Provisional filing fee |          |

SUBTOTAL (1)

(\$ )

### 2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

|                    | Extra Claims | Fees from below | Fee Paid |
|--------------------|--------------|-----------------|----------|
| Total Claims       |              |                 |          |
| Independent Claims |              |                 |          |
| Multiple Dependent |              |                 |          |

Large Entity Small Entity

| Fee Code | Fee (\$) | Fee Code | Fee (\$) | Fee Description  |
|----------|----------|----------|----------|--|
| 1202     | 18       | 2202     | 9        | Claims in excess of 20                                     |
| 1201     | 84       | 2201     | 42       | Independent claims in excess of 3                          |
| 1203     | 280      | 2203     | 140      | Multiple dependent claim, if not paid                      |
| 1204     | 84       | 2204     | 42       | ** Reissue independent claims over original patent         |
| 1205     | 18       | 2205     | 9        | ** Reissue claims in excess of 20 and over original patent |

SUBTOTAL (2)

(\$ )

\*\*or number previously paid, if greater. For Reissues, see above

## FEE CALCULATION (continued)

### 3. ADDITIONAL FEES

| Large Fee Code | Large Fee (\$) | Small Fee Code | Small Fee (\$) | Fee Description  | Fee Paid |
|----------------|----------------|----------------|----------------|--|----------|
| 1051           | 130            | 2051           | 65             | Surcharge - late filing fee or oath  |          |
| 1052           | 50             | 2052           | 25             | Surcharge - late provisional filing fee or cover sheet.                    |          |
| 1053           | 130            | 2053           | 65             | Non-English specification  |          |
| 1812           | 2,520          | 2812           | 1,260          | For filing a request for reexamination                                     |          |
| 1804           | 920*           | 2804           | 460*           | Requesting publication of SIR prior to Examiner action                     |          |
| 1805           | 1,840*         | 2805           | 920*           | Requesting publication of SIR after Examiner action                        |          |
| 125*           | 110            | 225*           | 55             | Extension for reply within first month                                     |          |
| 1252           | 410            | 2252           | 205            | Extension for reply within second month                                    |          |
| 1253           | 930            | 2253           | 465            | Extension for reply within third month                                     |          |
| 1254           | 1,450          | 2254           | 725            | Extension for reply within fourth month                                    |          |
| 1255           | 1,970          | 2255           | 985            | Extension for reply within fifth month                                     |          |
| 1401           | 320            | 2401           | 160            | Notice of Appeal   |          |
| 1402           | 320            | 2402           | 160            | Filing a brief in support of an appeal                                     |          |
| 1403           | 280            | 2403           | 140            | Request for oral hearing   |          |
| 1451           | 1,510          | 2451           | 755            | Petition to institute a public use proceeding                              |          |
| 1452           | 110            | 2452           | 55             | Petition to revive - unavoidable   |          |
| 1453           | 1,300          | 2453           | 650            | Petition to revive - unintentional   |          |
| 1501           | 1,300          | 2501           | 650            | Utility issue fee (or reissue)   |          |
| 1502           | 470            | 2502           | 235            | Design issue fee   |          |
| 1503           | 630            | 2503           | 315            | Plant issue fee  |          |
| 1460           | 130            | 2460           | 65             | Petitions to the Commissioner  |          |
| 1807           | 50             | 2807           | 25             | Petitions related to provisional applications                              |          |
| 1806           | 180            | 2806           | 90             | Submission of Information Disclosure Stmt                                  | 180      |
| 8021           | 40             | 28021          | 20             | Recording each patent assignment per property (times number of properties) |          |
| 1809           | 750            | 2809           | 375            | Filing a submission after final rejection (37 CFR § 1.129(a))              |          |
| 1810           | 750            | 2810           | 375            | For each additional invention to be examined (37 CFR § 1.129(b))           |          |
| 1301           | 750            | 2801           | 375            | Request for Continued Examination (RCE)                                    |          |
| 1302           | 900            | 2802           | 450            | Request for expedited examination of a design application                  |          |

Other fee (specify) \_\_\_\_\_

\*Reduced by Basic Filing Fee Paid SUBTOTAL (3)

(\$ )180

## SUBMITTED BY

Complete (if applicable)

Name (Print/Type) Scott L. Ausenhus Registration No. (Attorney/Agent) 42,271 Telephone 303-571-4000

Signature *Scott Ausenhus*

Date 9/30/03

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TOWNSEND and TOWNSEND and CREW LLP

By

Nicole M. Wartell

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

HIMMELSPACH et al.

Application No.: 09/632,722

Filed: August 4, 2000

For: FACTOR X ANALOG WITH AN  
IMPROVED ABILITY TO BE  
ACTIVATED

Examiner: Robinson, Hope A.

Art Unit: 1653

INFORMATION DISCLOSURE  
STATEMENT UNDER 37 CFR §1.97 and  
§1.98

Commissioner for Patents  
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Alexandria, VA 22313-1450

10/06/2003 MROCHA1 00000015 201430 09632722

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Sir:

The references cited on attached form PTO/SB/08A and PTO/SB/08B are being called to the attention of the Examiner. Copies of the references are enclosed.

It is respectfully requested that the cited references be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

As provided for by 37 CFR 1.97(g) and (h), no inference should be made that the information and references cited are prior art merely because they are in this statement and no

PATENT  
Attorney Docket No.: 20695C-005700US  
Client Reference No.: FA23500

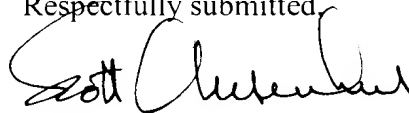
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representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information.

This IDS is being filed before the mailing date of the final Office Action or Notice of Allowance.

Please charge the IDS fee of \$180 to Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,



Scott L. Ausenhus  
Reg. No. 42,271

TOWNSEND and TOWNSEND and CREW LLP  
Two Embarcadero Center, 8<sup>th</sup> Floor  
San Francisco, California 94111-3834  
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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Sheet 1 of 3

**Complete if Known**

|                        |                   |
|------------------------|-------------------|
| Application Number     | 09/632,722        |
| Filing Date            | August 4, 2000    |
| First Named Inventor   | Himmelspach       |
| Art Unit               | 1653              |
| Examiner Name          | Robinson, Hope A. |
| Attorney Docket Number | 20695C-005700US   |

**U.S. PATENT DOCUMENTS+**

| Examiner<br>Initials* | Cite<br>No. <sup>1</sup> | Document Number |                                   | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines, Where<br>Relevant Passages or Relevant<br>Figures Appear |
|-----------------------|--------------------------|-----------------|-----------------------------------|--------------------------------|--|---|
|                       |                          | Number          | Kind Code <sup>2</sup> (if known) |                                |  |   |
|                       | A1                       | US-4,359,049    |                                   | 11-16-1982                     | Redl et al.  |   |
|                       | A2                       | US-4,501,731    |                                   | 02-26-1985                     | Tishkoff et al.                                    |   |
|                       | A3                       | US-4,735,616    |                                   | 04-05-1988                     | Eibl et al.  |   |
|                       | A4                       | US-5,460,950    |                                   | 10-24-1995                     | Barr et al.  |   |
|                       | A5                       | US-5,597,799    |                                   | 01-28-1997                     | Wolf   |   |
|                       | A6                       | US-5,635,481    |                                   | 06-03-1997                     | Wolf   |   |
|                       | A7                       | US-5,858,658    |                                   | 01-12-1999                     | Haemmerle et al.                                   |   |
|                       | A8                       | US-6,210,929 B1 |                                   | 04-03-2001                     | Schlok et al.                                      |   |
|                       | A9                       | US-6,562,598 B1 |                                   | 05-13-2003                     | Himmelspach et al.                                 |   |

**FOREIGN PATENT DOCUMENTS**

| Examiner<br>Initials* | Cite<br>No. <sup>1</sup> | Foreign Patent Document   |                     |                                   | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited<br>Document | Pages, Columns, Lines,<br>Where Relevant<br>Passages or Relevant<br>Figures Appear | T <sup>6</sup>           |
|-----------------------|--------------------------|---------------------------|---------------------|-----------------------------------|--------------------------------|---|--|--------------------------|
|                       |                          | Country Code <sup>3</sup> | Number <sup>4</sup> | Kind Code <sup>5</sup> (if known) |                                |   |  |                          |
|                       | B1                       | EPO                       | EP 0 651 054        | A1                                | 03-05-1995                     |   |  | <input type="checkbox"/> |
|                       | B2                       | PCT                       | WO 94/29370         | A1                                | 12-22-1994                     |   |  | <input type="checkbox"/> |

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Sheet 2 of 3

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|                        |                   |
|------------------------|-------------------|
| Application Number     | 09/632,722        |
| Filing Date            | August 4, 2000    |
| First Named Inventor   | Himmelspach       |
| Art Unit               | 1653              |
| Examiner Name          | Robinson, Hope A. |
| Attorney Docket Number | 20695C-005700US   |

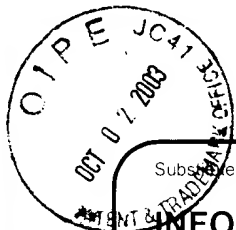
**NON PATENT LITERATURE DOCUMENTS**

| Examiner<br>Initials * | Cite<br>No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item<br>(book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s),<br>publisher, city and/or country where published. | T <sup>2</sup> |
|------------------------|--------------------------|---|----------------|
|                        | C1                       | BAJAJ, S. & MANN, K. "Simultaneous Purification of Bovine Prothrombin and Factor X." <i>J. Biol. Chem.</i> , November 25, 1973, pp. 7729-7741, Vol. 248, No. 22.  |                |
|                        | C2                       | BARR, P. J. "Mammalian Subtilisins: The Long-Sought Dibasic Processing Endoproteases." <i>Cell</i> , 1991, pp. 1-3, Vol. 66.  |                |
|                        | C3                       | CLACKSON, T. et al. <i>PCR A Practical Approach, General Applications of PCR to Gene Cloning and Manipulation</i> , Eds. McPherson, Quirke and Taylor, 1991, pp. 187-214.   |                |
|                        | C4                       | EBY, C. S. et al. "Characterization of the Structure and Function of the Carboxy Terminal Peptide of Human Factor X." <i>Blood</i> , 1992, pp. 1214, Vol. 80, Suppl. 1, Abstract only.  |                |
|                        | C5                       | ELSINGER, R. <i>Laboratory Tests of Activated Prothrombin Complex Preparations; Activated Prothrombin Complex Concentrates</i> , 1982, pp. 77-87 Chapter 11, Eds. Mariani, Russo and Mandelli, Praeger Publishers, U.S.A.   |                |
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|                        | C8                       | FUNG, M. et al. "Characterization of an almost full-length cDNA coding for human blood coagulation factor X." <i>Proc. Natl. Acad. Sci. USA</i> , June 1985, pp. 3591-3595, Vol. 82.  |                |
|                        | C9                       | GILES, A. et al. "A combination of factor Xa and phosphatidylcholine-phosphatidylserine vesicles bypasses factor VIII in vivo." <i>British J. Haematology</i> , 1988, pp. 491-497, Vol. 69.   |                |
|                        | C10                      | GORDON, V. M. et al. "Proteolytic Activation of Bacterial Toxins by Eukaryotic Cells is Performed by Furin and by Additional Cellular Proteases." <i>Infect. Immunol.</i> , 1995, pp. 82-87, Vol. 63.   |                |
|                        | C11                      | HIMMELSPACH, M. et al. "Alteration of the Specificity of FX Activation by Substitution of Amino Acids Constituting its Activation Site", <i>XVII Congress of the International Society on Thrombosis and Haemostasis</i> , 1999, p. 758.                              |                |
|                        | C12                      | JESTY, J. et al. "The Mechanism of Activation of Factor X: Kinetic Control of Alternative Pathways Leading to the Formation of Activated Factor X." <i>J. Biol. Chem.</i> , September 10, 1974, pp. 5614-5622, Vol. 249, No. 17.                                      |                |
|                        | C13                      | LEYTUS, S. et al. "Characterization of cDNA coding for human factor X." <i>Proc. Natl. Acad. Sci. USA</i> , June 1984, pp. 3699-3702, Vol. 81.  |                |
|                        | C14                      | LEYTUS, S. et al. "Gene for Human Factor S: A Blood Coagulation Factor Whose Gene Organization is Essentially identical with that of Factor IX and Protein C." <i>Biochem.</i> , 1986, pp. 5098-5102, Vol. 25.  |                |
|                        | C15                      | MERTENS, K. & BERTINA, R. "Pathways in the Activation of Human Coagulation Factor X" <i>Biochem. J.</i> , 1980, pp. 647-658, Vol. 185.  |                |
|                        | C16                      | MESSIER, T. et al. "Cloning and expression in COS-1 cells of a full-length cDNA encoding human coagulation factor X." <i>Gene</i> , 1991, pp. 291-294, Vol. 99, Elsevier.   |                |
|                        | C17                      | MOEHRING, J. M. & MOEHRING, T. J. "Strains of CHO-K1 Cells Resistant to Pseudomonas Exotoxin A and Cross-Resistant to Diphtheria Toxin and Viruses." <i>Infection and Immunity</i> , 1983, pp. 998-1009, Vol. 41.   |                |

Examiner  
SignatureDate  
Considered

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Sheet 3 of 3

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|------------------------|-------------------|
| Application Number     | 09/632,722        |
| Filing Date            | August 4, 2000    |
| First Named Inventor   | Himmelspach       |
| Art Unit               | 1653              |
| Examiner Name          | Robinson, Hope A. |
| Attorney Docket Number | 20695C-005700US   |

**NON PATENT LITERATURE DOCUMENTS**

| Examiner<br>Initials * | Cite<br>No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T <sup>2</sup> |
|------------------------|--------------------------|---|----------------|
|                        | C18                      | MORITA et al. "Structural and Functional Characteristics of a Proteolytically Modified 'Gla Domain-less' Bovine Factor X and Xa (des light chain residues 1-44)." <i>General Biochem.</i> 1980, p. 219, Vol. 92, Abstract No. 92 71374k.                        |                |
|                        | C19                      | NGO et al. <u>Computational Complexity, Protein Structure Prediction and the Levinthal Paradox in the Protein Folding Problem and Tertiary Structure</u> , 1994, Eds. K. Mez, Jr. and Le Grand, Birkhauser, Boston.   |                |
|                        | C20                      | OHNISHI, Y. et al. "A Furin-Defective Cell Line is Able to Process Correctly the gp160 of Human Immunodeficiency Virus Type 1." <i>J. Virol.</i> , 1994, pp. 4075-4079, Vol. 68.  |                |
|                        | C21                      | PRYZDIAL, E. & FESSLER, G. "Autoproteolysis or Plasmin-mediated Cleavage of Factor Xa Exposes a Plasminogen Binding Site and Inhibits Coagulation." <i>J. Biol. Chem.</i> , July 12, 1996, pp. 16614-16620, Vol. 271, No. 28.                                   |                |
|                        | C22                      | PRYZDIAL, E. & FESSLER, G. "Kinetics of Blood Coagulation of Factor Xa Autoproteolytic Conversion of Factor Xa." <i>J. Biol. Chem.</i> , July 12, 1996, pp. 16621-16626, Vol. 271, No. 28.  |                |
|                        | C23                      | PEHEMULLA, A. & KAUFMAN, R.J. "Preferred Sequence Requirements for Cleavage of Pro-von Willebrand Factor by Propeptide-Processing Enzymes" <i>Blood</i> , 1992, pp. 2349-2355, Vol. 79.   |                |
|                        | C24                      | RUDOLPH, A.E. et al. "Expression, Purification and Characterization of Recombinant Human Factor X <sup>1</sup> ." <i>Protein Expression and Purification</i> , 1997, pp. 373-378, Vol. 10.  |                |
|                        | C25                      | SHERPILL, G.B. et al. "Inactivation of Human Blood Coagulation Factor X by Chemical Modification of Gamma-Carboxyglutamic Acid Residues" <i>Enzymes</i> , 1985, p. 239, Vol. 102, Abstract No. 102.2489q.   |                |
|                        | C26                      | TENG, C. & SEEGER, W. "Production of factor X and factor Xa variants with thrombin, acutin and by autolysis." <i>Thrombosis Research</i> 1981, pp. 213-220, Vol. 22.  |                |
|                        | C27                      | URLAUB, G. & CHASIN, L. "Isolation of Chinese hamster cell mutants deficient in dihydrofolate reductase activity." <i>Proc. Natl. Acad. Sci. USA</i> , July 1980, pp. 4216-4220, Vol. 77, No. 7.  |                |
|                        | C28                      | WALLIN, R. et al. "Intracellular Proteolytic Processing of the Two-Chain Vitamin K-Dependent Coagulation Factor X." <i>Thrombosis Res.</i> , 1994, pp. 395-403, Vol. 73.  |                |
|                        | C29                      | WATZKE, H. & HIGH, K. "Factor X." <i>Molecular Basis of Thrombosis and Hemostasis</i> , 1995, pp. 239-255, Chapter 11, Eds. High and Roberts.   |                |
|                        | C30                      | WELLS et al. "Additivity of Mutational Effects in Proteins" <i>Biochemistry</i> , 1990, pp. 8509-8517, Vol. 29, No. 37.   |                |
|                        | C31                      | WOLF, D. et al. "Design of Constructs for the Expression of Biologically Active Recombinant Human Factors X and Xa" <i>J. Biol. Chem.</i> , July 25, 1991, pp. 13726-13730, Vol. 266, No. 21.   |                |

|                       |  |                    |  |
|-----------------------|--|--------------------|--|
| Examiner<br>Signature |  | Date<br>Considered |  |
|-----------------------|--|--------------------|--|

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